REMARKS

This paper is responsive to the Office Action dated April 20, 2004, which is the first action on the merits of the application.

Claims 1-20 were previously pending in the application, and subject to a restriction requirement. Claims 1-2 (in part), 3-4, 5-7 (in part), 10-15 (in part), and 16-17 were under examination with respect to the invention of Group II of the Restriction Requirement; the other claimed subject matter was not considered. Upon entry of this Amendment, claim 8 is canceled, and claim 21 is added.

As explained below, the subject matter of all amended claims except claims 9 and 18-20 cover subject matter in Group II. Accordingly, claims 1-7, 10-17, and 21 are all under examination in whole or in part. The non-elected subject matter claimed in this application is the subject of a request for rejoinder.

Further consideration and allowance of the application is respectfully requested.

Amendments:

The amendments to the specification do not incorporate new matter into the disclosure. The amendment to paragraph [0010] and the insertions made after paragraph [0051] are taken from U.S. Patent No. 6,166,178 at col. 3, lines 5358, and at col. 138, line 22 to col. 139, line 54. The '178 patent (USSN 08/974,549) was incorporated into the present application by reference in paragraph [0001] when the application was filed. Other amendments are made to update information on prior patent applications and address other minor issues.

The amendments to the claims also do not incorporate new matter into the disclosure. The amendments to claims 1, 2, and 16 are supported throughout the description, examples, and tables of the application as filed, such as paragraph [0010], and the subject matter incorporated by reference from U.S. Patent No. 6,166,178. New claim 21 is supported *inter alia* by claim 12 as previously presented.

Substitute Specification

A Substitute Specification will be provided to the Office under separate cover, incorporating all of the specification and claim amendments made previously and herein.

Substitute Sequence Listing

Now that applicant has received clarification of the errors detected by the Office in the sequence listing supplied with the filed application, the Substitute Specification incorporates the corrections to the numbering of amino acids 1025 and 1105 of SEQ. ID NO:2.

The STIC Systems Branch indicates that the two "obvious mistakes" have been "corrected". Accordingly, applicant understands that the Office has an accurate and properly formatted sequence listing in electronic form, and has already conducted a sequence search to the extent necessary to determine the patentability of this invention. Of course, applicant will gladly provide a replacement sequence listing on diskette upon request.

Objections:

The specification is objected to for the definition of the term "corresponds". The sentence objected to has now been removed. The undersigned is not currently aware of any other minor errors.

Rejections under 35 USC § 112 ¶ 2:

Claim 1 stands rejected under § 112 ¶ 2 for a purported ambiguity as to what deletions may or may not be included in the claimed invention. The amendments made to claim 1 are believed to address the issue raised.

Claims 1 and 16 stand rejected because hybridization conditions were not explicitly indicated. In fact, stringent hybridization conditions are explicitly defined in the previous applications incorporated into the present disclosure by reference. The conditions have now been explicitly written into both the specification and the claims.

Claims 5-7 and 13-17, (and separately claim 14) stand rejected on the basis that a "dominant negative mutant" necessarily inhibits telomerase activity.

Applicant respectfully disagrees. Since the term "dominant negative mutant" is recited in dependent claim 5, the question is whether this term further limits the telomerase inhibiting compound

of claim 1. In fact, it does, because the terms are not synonymous — not all inhibiting compounds are dominant negative mutants. In fact, the skilled reader will understand that a "dominant negative mutant" must be able to effectively inhibit the native form of the molecule *by at least 50%* when both are present in equimolar quantities. *If it did not inhibit the natural form by at least 50%, then it would not be "dominant".* On the other hand, a molecule that substantially inhibits the native form only at a higher molar ratio would meet the definition of being a telomerase inhibitor, but not of being a dominant negative mutant.

Claim 5 has been amended so as not to refer to both a "dominant negative mutant" and a "peptide mimetic". All of the other claims have been amended so as to remove the term "dominant negative mutant".

Claims 11 and 13-17 stand rejected for use of phrases including the word "means". This is addressed in the section addressed to *means plus function claims* later in this Response.

Claims 1-3, 5-7, 16, and 17 stand rejected under § 112 ¶ 2 for use of the limitation "deletions consisting essentially of" [certain amino acid residues].

Applicant respectfully disagrees. The skilled reader will appreciate the term to mean that the user will make the deletions to the same regions of the TRT protein indicated in the claim, but has the option of making minor adjustments in the exact length of the deletion so long as it has the same effect of inactivating the reverse transcriptase activity of the protein. Applicant seeks this coverage so as to adequately protect the invention. Now that the inventors have shown where the functionally sensitive regions are located within the 1132 amino acids of the TRT molecule, the skilled reader may readily tinker with deletions in the same regions without undue experimentation, expecting the same result.

Withdrawal of these rejections is respectfully requested.

Rejections under 35 USC § 112 ¶ 1:

Claims 1-3, 5-7, and 10-17 stand rejected under the written description requirement of § 112 ¶ 1. Specifically, the Office Action objects to the description of the peptides as "comprising at least 25 consecutive amino acids. The same claims stand rejected under the enablement requirements of § 112 ¶ 1. Specifically, the Office Action indicates that a large amount of screening would be required to obtain the dominant negative mutants that are claimed.

The independent claims have now been amended to indicate that the peptide consists of at least 500 consecutive amino acids if SEQ. ID NO:2. A clean copy of claims 1 and 2 incorporating all the amendments is provided below for the convenience of the Examiner.

1. A protein, peptide, or peptide mimetic that inhibits human telomerase, which has a sequence consists of at least 500 consecutive amino acids encoded by DNA that hybridizes to a sequence complementary to SEQ. ID NO:1 at 5°C to 25°C below T_m in aqueous solution at 1 M NaCl,

wherein T_m is the melting temperature of double-stranded DNA having the sequence of SEQ. ID NO:1 under the same reaction conditions;

except that said protein, peptide, or peptide mimetic contains one or more deletions, each of which consists essentially of:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450,

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116

of SEQ. ID NO:2.

2. A protein, peptide, or peptide mimetic that inhibits human telomerase, which has a sequence consisting of at least 500 consecutive amino acids of SEQ. ID NO:2; except that it contains one or more deletions, each of which consists essentially of:

a) residues 560-565,

b) residues 930-934, or

c) at least 10 consecutive amino acids from residues 323-450,

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116

of SEQ. ID NO:2.

Applicant respectfully submits that the amended claims are directed to aspects of the invention that are fully described and enabled by the description as filed.

The Office Action also raises concerns as to whether the 15 introns in the gene are adequately described. Of course, the introns are features of the gene, and not part of the translated protein. The reader is directed by the specification and the claim to put one or more deletions in the specified

regions of the prototype translation product (SEQ. ID NO:2), irrespective of where the introns may occur. Proteins comprising deletions in the specified regions of SEQ. ID NO:2 were clearly in possession of the inventors.

The skilled reader will know to make a protein that inhibits human telomerase according to the invention by first obtaining a polynucleotide that encodes SEQ. ID NO:2 (as provided in the specification), deleting one or more parts of the encoding sequence corresponding to regions a) to g) of the claims, expressing the polynucleotide in a cell also expressing telomerase RNA component, and then testing the cell to ensure that the protein is being produced, but no telomerase activity results. This can be done in the manner illustrated in Section IV (paragraphs [0038] to [0048]) of the specification. Optionally, the reader may introduce further alterations into the sequence by random or site-directed mutagenesis, so that the protein differs at other points in the amino acid sequence, but still is encoded by a polynucleotide that hybridizes to SEQ. ID NO:1 under the conditions indicated in claim 1.

Accordingly, the invention presented in the amended claims is fully described and enabled by the specification as filed. Withdrawal of this rejection is respectfully requested.

Means plus function claims:

Claim 13 and its dependents stand rejected under both 35 USC § 112 ¶¶ 1 and 2 in relation to reference to the protein, peptide, and peptide mimetics of the invention having a means for inhibiting telomerase activity, and/ or a means for binding telomerase RNA component.

In fact, claiming an invention in terms of means plus function is explicitly provided for in 35 USC § 112 ¶ 6:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The wording of claim 13 explicitly invokes § 112 ¶ 6. Applicant hereby requests that claim 13 and its dependents be examined in accordance with § 112 ¶ 6.

The proper test for meeting the definiteness requirement is that the corresponding structure of a means plus function limitation need only be disclosed in the specification in a way that one skilled in the art will understand what structure will perform the recited function. *Atmel Corp. v. Information*

Storage Devices, Inc., 53 USPQ2d 1225, 1230 (Fed. Cir. 1999). For examination of means plus function limitations under § 112 ¶ 6, the Examiner is respectfully referred to MPEP § 2181. The requirements for means plus function limitations under § 112 ¶¶ 1 and 2 are elucidated in MPEP § 2181 (III) and (IV).

Applicant respectfully submits that a *means for inhibiting telomerase activity* as referred to in the claims are exemplified sufficiently in the specification and in the dependent claims so that the skilled reader will understand what structure is meant. Accordingly, the claims meet the requirements of § 112 ¶ 6 and § 112 ¶ 2. Since the exemplary structures are described and enabled in the specification, they also meet the requirements of § 112 ¶ 1.

Withdrawal of these rejections is respectfully requested.

Restriction Requirement and Request for Rejoinder:

In the Restriction Requirement mailed October 3, 2004, applicant understood the group elected for examination (Group II) to include polypeptides encoded in a polynucleotide that hybridizes under stringent conditions to the complement of SEQ. ID NO:1; but which contains one or more deletions in certain regions of the molecule — along with methods of use.

The claims have now been amended so that the subject matter of the elected group includes the following:

- Claims 1 to 7, 10, 12, and 16 to 17, in their entirety
- Claims 9, 11, 13 to 15, and 21 in part

The claims withdrawn in their entirety are:

- Claims 18-20

Independent claim 13, and dependent claims 9, 11, 14, 15, and 21 serve the function of linking the species in the elected group and the group withdrawn from examination.

Accordingly, applicant respectfully requests that the withdrawn subject matter be rejoined into the group under examination, upon determination that the group under examination is free of prior art.

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Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

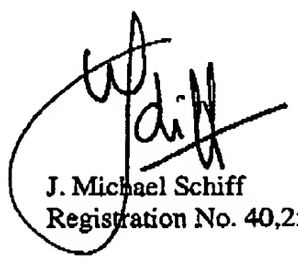
Fees Due

No fee is required with respect to the amendments to the claims, since the claim count has not changed.

Enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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